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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/549,321	09/16/2005	Tatsuo Horizoe	0425-1214PUS1	8222
2292 7590 01/30/2008 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747			EXAMINER SPIVACK, PHYLLIS G	
			ART UNIT 1614	PAPER NUMBER
			NOTIFICATION DATE 01/30/2008	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No. 10/549,321	Applicant(s) HORIZOE, TATSUO	
	Examiner Phyllis G. Spivack	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) 11-15, 18 and 24-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 16, 17 and 19-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>9-6-05</u> . | 6) <input type="checkbox"/> Other: _____ |

A Preliminary Amendment filed September 16, 2005 is acknowledged in which multiple dependencies were removed. Claims 1-29 are presented.

In response to the Restriction/Election Requirements mailed November 5, 2007, Applicant elected without traverse Group I, claims 1-10, 16, 17 and 19-23, and sulfasalazine as a specie of the claimed aminosalicyclic acid derivative and compound 10 of claim 5, 3-{3-[3-(4-chloro-2-cyanophenoxy)-2(S)-isopropoxy]phenyl}-2(S)-isopropoxypropanoic acid, on December 5, 2007.

Accordingly, the subject matter under initial examination are those agents for treating an inflammatory bowel disease comprising a combination of sulfasalazine and 5, 3-{3-[3-(4-chloro-2-cyanophenoxy)-2(S)-isopropoxy]phenyl}-2(S)-isopropoxypropanoic acid, claims 1-10, 16, 17 and 19-23. The subject matter under initial consideration is entirely drawn to **composition** claims. Claims 11-15, 18 and 24-29 are withdrawn from consideration by the Examiner, 37 CFR 1.142(b), as drawn to non-elected subject matter. Re-affirmation of the elections is requested when Applicant responds to this Office Action.

Information Disclosure Statements filed September 16, 2005 and March 3, 2006 are further acknowledged and have been reviewed.

Claims 4 and 19-22 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claims, or amend the claims to place the claims in proper dependent form, or rewrite the claims in independent form.

Intended use (recited in claims 4, 19 and 20) confers no patentable weight to composition claims. See *In re Hack*, 114 USPQ 161. Merely reciting the intended use of an old composition does not impart patentability thereto.

Claim 23 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Claim 23 recites the limitation "successive administration." There is insufficient antecedent basis for this limitation in the claim.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-10, 16, 17 and 19-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over The Merck Manual, in view of Matsuura et al., US 2004/0102634.

The Merck Manual clearly teaches combination therapy for the treatment of inflammatory bowel diseases, such as Crohn's disease and ulcerative colitis. The aminosalicylic acid derivative, sulfasalazine is a part of recognized drug protocols for both bowel diseases. See, in particular, pages 306 and 310-311.

Matsuura teaches the administration of the elected specie compound, 3-{3-[3-(4-chloro-2-cyanophenoxy)-2(S)-isopropoxy]phenyl}-2(S)-isopropoxypropanoic acid, specifically to treat ulcerative colitis and Crohn's disease. See Example 323, page 115, and page 189, claim 57.

It is generally obvious to combine two active agents, each of which is individually known to be useful in the treatment of the same condition. *In re Kerhoven*, 205 USPQ 1069 (CCPA 1980). The idea for combining said agents flows logically from their having been individually taught in the prior art. *In re Crockett*, 126 USPQ 186, 188 (CCPA 1960). Accordingly, to establish obviousness in such fact situations it is not necessary that motivation comes explicitly from the reference itself. The natural presumption that two individually known anti-inflammatory agents useful in the treatment of inflammatory bowel diseases would, when combined, provide a third composition that is also for treating inflammatory bowel diseases flows logically from each having been individually taught in the prior art. Thus in the absence of a showing of unexpected results commensurate in scope with the claims, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine the aminosalicylic acid derivative, sulfasalazine, and 3-{3[3-(4-chloro-2-cyanophenoxy)-2(S)-isopropoxy]phenyl}-2(S)-isopropoxypropanoic acid for the treatment of inflammatory bowel diseases.

In view of the combined teachings of The Merck Manual and Matsuura, the skilled artisan in formulation chemistry would have been motivated to prepare a combination agent comprising sulfasalazine and 3-{3[3-(4-chloro-2-cyanophenoxy)-2(S)-isopropoxy]phenyl}-2(S)-isopropoxypropanoic acid to treat ulcerative colitis or Crohn's disease. The prior art (Merck) is very clear that it is beneficial to combine drugs in order to provide an efficacious treatment modality for patients suffering from inflammatory bowel diseases.

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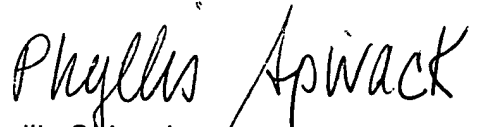
No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached from 10:30 to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Ardin Marschel, can be reached 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

January 17, 2008


Phyllis Spivack **PHYLLIS SPIVACK**
PRIMARY EXAMINER